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DATE: 12/1/97TO: Examiner S. maki/Art Unit 1301

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FROM: Philip C. StrassburgerTOTAL PAGES (INCLUDING COVER SHEET): 6COMMENTS: Serial No. 08/692, 314Attorney Docket No. PC7558D**OFFICIAL**

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Docket No. PC7558D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) I hereby certify that this correspondence
Robert N. Hamlin) is being telefaxed to:
Serial No.: 08/692,314) Assistant Commissioner For Patents
Filed: August 5, 1996) Washington, D.C. 20231
For: METHOD OF MAKING A) Attention: Examiner S. Maki
MULTILAYER ANGIOPLASTY) Art Unit: 1301
CATHETER BALLOON)
(AS AMENDED)) on December 1, 1997 at (703) 305-7115

Liz DeMinico

(Name)



December 1, 1997

(Date of Signature)

Assistant Commissioner for Patents
Washington, D.C. 20231

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Sir:

RESPONSE AFTER FINAL REJECTION

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Applicant appreciates the courtesy extended by Examiner Maki during the personal interview of July 15, 1997 and the subsequent telephone interview of July 30, 1997. Receipt of the corresponding Examiner Interview Summary Records is acknowledged (papers no. 35 and 38-1/2, respectively).

Subsequent to the telephone interview of July 30, 1997, Applicant submitted a Supplemental Amendment. That Amendment was filed solely to expeditiously obtain the priority of parent application serial no. 07/411,649 under 35 U.S.C. § 120. The Supplemental Amendment was not filed in response to rejections under 35 U.S.C. § 103.

Receipt of the Office Action mailed November 14, 1997 (paper no. 41) is also acknowledged. The following claims are pending: 116, 118-125, 127, 128, 130-134, 136-143, 145-146, and 148-165. It is appreciated that the Examiner has withdrawn all of the rejections under 35 U.S.C. § 112 and most of the rejections under 35 U.S.C. § 103. Reconsideration of

the remaining rejections and allowance of the claims is respectfully requested in view of the following remarks.

The pending claims stand rejected under 35 U.S.C. § 103 as allegedly obvious from Levy (U.S. Patent Nos. 4,490,421, Re 32,983 and Re 33,561) in view of Japanese Laid-Open Patent Application No. 58-188463, "Coextruded Composite Film" by Parker, Patel (U.S. Patent No. 4,335,723), and optionally in view of Dyke (U.S. Patent No. 4,003,382) and/or Japanese Patent Application 53-45353. Applicant respectfully disagrees primarily because there is no teaching or suggestion to combine the cited documents.

(A) Levy does not Teach or Suggest a Multi-Layer Balloon

Levy's disclosure is limited to a single-layer balloon. With reference to U.S. Patent No. 4,490,421, the essence of Levy is a selection of one polymer: "The process by which the balloon is prepared can be carried out in a conventional manner with conventional equipment using a *specialized polymer* as the material of fabrication" (3:31-34, emphasis added). Only a single layer is disclosed (see Figure 1).

In selecting his specialized polymer, Levy rejected certain polymers which were purportedly disclosed in prior art patents, namely: "ethylene-butylene-styrene block copolymers admixed with low molecular weight polystyrene and, optionally, polypropylene, and similar compositions employing butadiene or isoprene in place of the ethylene and butylene; poly (vinyl chloride); polyurethanes; copolyesters; thermoplastic rubbers; siliconepolycarbonate copolymers; and ethylene-vinyl acetate copolymers" (1:31-39). Thus, Levy teaches a single layer balloon made of one material in lieu of another material. He does not suggest a multilayer balloon such as the multilayer polyester/PVC balloon claimed by Applicant in claims 124 and 142 or the multilayer polyester/polyurethane balloon claimed by Applicant in claims 125 and 143, since Levy has specifically rejected PVC and polyurethane as balloon materials.

In sum, Levy discloses a single layer balloon made of a single specialized polymer, and teaches away from a multilayer balloon.

(B) Japanese Patent Application No. 58-188463 teaches away from Levy

Japanese patent application no. 58-188463 relates to a balloon which can be made of certain materials which were specifically rejected by Levy. With reference to the English Translation, the balloon may include polyvinyl chloride, polyurethanes, latex rubber, or silicone rubber (page 2, line 4). As discussed above, Levy distinguished his *specialized polymer* from such polymers.

The '463 application also relates to a relatively low pressure balloon for anesthetic or respiratory use. Its statement of "Problems of the Existing Technology" identifies high pressure against the tracheal wall as a problem which can cause "insufficient peripheral circulation in the tracheal mucosa...." (page 3, lines 12-15). The Japanese application purports to prevent diffusion into the balloon, which would increase pressure (page 3, line 23 - page 4, line 11). Thus, this document teaches away from the relatively high pressure balloons of Levy.

Further, the '463 application does not teach or suggest combination with the extrusion process of Levy. Rather, a molding/coating process is described (page 6 line 26 to page 7, line 6). In fact, the above-referenced latex and silicone rubber materials cannot be readily extruded by the process set forth in Levy to form a catheter balloon. Also, the '463 application describes a two-stepped process for making the multi-layer balloon ("a soft synthetic resin is formed in advance into a balloon shape," page 2, lines 11-12).

Thus, the '463 application teaches away from combination with Levy in several regards.

(C) Parker does not teach or suggest combination with Levy or the '463 application

Parker is limited to packaging. It does not teach or suggest combination with a medical balloon disclosure.

Further, Parker teaches collapsing its extruded film "into a layflat tubing" (Column 2, lines 12-13). Such a teaching, which is consistent with a packaging disclosure, renders the disclosure useless and uncombinable with disclosures relating to inflatable medical balloons.

(D) Patel Teaches Away From a Multilayer Balloon

Patel (U.S. Patent No. 4,335,723) teaches a single layer balloon (see Figures 1-2 and 5). One skilled in the art would not ignore this balloon teaching in favor of Patel's shaft teaching, and then apply the shaft teachings to a balloon disclosure. This is especially so because of the substantial structural differences between catheter shafts and inflatable catheter balloons.

Further, Patel teaches away from latex and silicone rubbers (1: 50-57) which are deemed in the '463 Japanese application to be acceptable materials.

Thus, Patel teaches away from combination with both Levy and the '463 application.

In sum, there is no teaching or suggestion to combine the four above-referenced documents. Each document is disjointed from the others and generally teach away from combination with one another. It is only in hindsight, and with reference to applicant's invention, that one would pick and choose from among the cited documents in an attempt to recreate the present invention. In view of the deficiencies of the four above-referenced documents, Applicant submits that it is unnecessary to discuss the two optional documents cited by the Examiner.

The Examiner states that the "the prior art as a whole suggests/motivates forming a two layer balloon by the known technique of coextrusion in order to improve the impermeability (Japan '463/Parker) and adherability (Parker/Patel/Japan '353) of a high burst pressure balloon formed by the process of Levy" (paper no. 41, page 5, lines 12-16). Applicant disagrees primarily for the reasons stated above, namely, the documents generally teach away from combination. In any event, it would be improper to use two distinct bases for

combination (impermeability to combin Japan '463 and Parker and then adhesibility to combine Parker, Patel and Japan '353) where there is no suggestion that such distinct bases should be combined. This would be tantamount to "combining combinations." There is no suggestion to combine the alleged bases here, where common document Parker teaches collapsing its extruded film into a layflat tubing and primary document Levy is silent with regard to both alleged bases for combination.

Applicant respectfully disagrees with the Examiner's comments at page 5, line 17 to page 6, line 13. These comments have been rendered moot so no discussion is necessary.

Applicant respectfully disagrees with the rejections of the dependent claims at page 6, line 14 to page 8, line 14. However, these dependent claims are allowable for the reasons cited above and no further discussion is necessary.

Thus, a *prima facie* case of obviousness has not been established and the claims are in condition for allowance. Such favorable action is earnestly solicited.

The undersigned respectfully requests a personal interview to discuss the foregoing remarks. Examiner Maki is kindly asked to contact the undersigned at (612) 550-5534 to schedule an interview. Thank you.

Respectfully submitted,

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